K120727 1/2

Summary of Safety and Effectiveness

Date: August 13, 2012

AUG 15 2012

Manufacturer:
Encore Medical, L.P.
Trade Name: DJO Surgical
9800 Metric Blvd
Austin, TX 78758

Contact Person:
William Garzon
Regulatory Affairs Specialist
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Product	Product Code	Regulation and Classfication Name
Movation Highly Cross Linked Vitamin E Tibial Insert	JWH, OIY	Knee Joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis per 21 CFR 888.3560

Legally Marketed Devices to which Substantial Equivalence is Claimed:

Movation Knee	K100900	DJO Surgical
HXL Vitamin E Tibial Insert	K091956	DJO Surgical

Description: The Movation Highly Cross Linked Vitamin E Tibial Inserts are manufactured from HXL VE (75KgY) ultra high molecular weight polyethylene (UHMWPE). The tibial inserts are available in 11 sizes (1,2,3,4,5,6,7,8,10,12, and 14) and 6 thicknesses (9mm – 21mm) and are provided neutral in orientation. The tibial insert is identical in design to the compression molded UHMWPE Movation tibial insert cleared via K100900. The tibial insert is identical in materials to the Highly Cross-Linked Vitamin E UHMWPE Tibial Insert cleared via K091956.

The Movation Knee System is Indicated for:

Joint replacement is indicated for patients suffering from disability due to:

- degenerative, post-traumatic or rheumatoid arthritis;
- avascular necrosis of the femoral condyle;
- post-traumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy;
- moderate valgus, varus or flexion deformities;
- treatment of fractures that are unmanageable using other techniques.

This device may also be indicated in the salvage of previously failed surgical attempts. This system is to be used for cemented applications.

Comparable features to Predicate Device: Features comparable to predicate devices include same design, intended use and sterilization method.

Summary of Technologies: The Movation HXL VE Tibial Inserts are infused with a vitamin E to stabilize free-radicals and prevent oxidative degredation and then highly cross-linked to improve wear resistance. The design feature Highly Cross-Linked Vitamin Polyethylene Material UHMWPe (α-tocopherol) is equivalent to the Highly Cross-Linked Vitamin E UHMWPE Tibial Insert cleared via K091956. The Movation HXL VE Tibial Inserts are attached to the baseplate via a super locking snap feature, equivalent to the Movation Knee cleared via K100900.

Non-Clinical Testing: The following non-clinical laboratory testing was performed to determine substantial
equivalence: mechanical material characterization (Tensile, Small Punch, Izod Impact, and crack propagation), physical and chemical characterization (Oxidation Index, Compressive Modulus, Poisson's Ratio, Surface Roughness, Density, Onset Melting Temperature, Peak Melting Temperature, Delta H, Degree of Crystallinity, Crosslink Density, Swell Ratio, Molecular Weight, Polydispersity Index, Lamallae Thickness, Free Radical Concentration, Vitamin E Concentration, Vitamin E Consolidation, Vitamin E Elution/Extraction, Trans-vinylene Index), tibial insert peel-out strength, wear testing, and biocompatibility. All testing has demonstrated the device is substantially equivalent to the predicate devices.

Clinical Testing: None provided

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Encore Medical, L.P.
% Mr. William Garzon
Regulatory Affairs Specialist
9800 Metric Boulevard
Austin, Texas 78758

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Re: K121727
Trade/Device Name: Movation Highly Crossed Linked Vitamin E Tibial Insert
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: OIY, JWH
Dated: July 13, 2012
Received: July 16, 2012

Dear Mr. Garzon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K121727

Device Name: Movation Highly Cross Linked Vitamin E Tibial Insert

Indications for Use:

The Movation Knee System is Indicated For:
Joint replacement is indicated for patients suffering from disability due to:

- degenerative, post-traumatic or rheumatoid arthritis;
- avascular necrosis of the femoral condyle;
- post-traumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy;
- moderate valgus, varus or flexion deformities;
- treatment of fractures that are unmanageable using other techniques.

This device may also be indicated in the salvage of previously failed surgical attempts. This system is to be used for cemented applications.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K121727